PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION See Form PCT/IPEA/416	
TP102882_MLA		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/FI 2004/050034	02-04-2004	10-04-2003
International Patent Classification (IPC) or national classification and IPC		
A61B 5/0452		
Applicant		
Korhonen, Pentti		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *(sent to the applicant and to the International Bureau)* a total of _____ sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s))
      _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
   - ☒ Box No. I Basis of the report
   - ☐ Box No. II Priority
   - ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - ☐ Box No. IV Lack of unity of invention
   - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - ☐ Box No. VI Certain documents cited
   - ☐ Box No. VII Certain defects in the international application
   - ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
05-11-2004	14-03-2005
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. +46 8 667 72 88	Authorized officer Anna Malmberg/MN Telephone No. +46 8 782 25 00

Form PCT/IPEA/409 (cover sheet) (January 2004)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/FI 2004/050034

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3 and 23.1(b))
☐ publication of the international application (under Rule 12.4)
☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

☒ the international application as originally filed/furnished
☐ the description:
pages _____ as originally filed/furnished
pages* _____ received by this Authority on _____
pages* _____ received by this Authority on _____
☐ the claims:
pages _____ as originally filed/furnished
pages* _____ as amended (together with any statement) under Article 19
pages* _____ received by this Authority on _____
pages* _____ received by this Authority on _____
☐ the drawings:
pages _____ as originally filed/furnished
pages* _____ received by this Authority on _____
pages* _____ received by this Authority on _____
☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/figs _____
☐ the sequence listing *(specify)*: _____
☐ any table(s) related to the sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/figs _____
☐ the sequence listing *(specify)*: _____
☐ any table(s) related to the sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/FI 2004/050034

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 1-18

because:

☒ the said international application, or the said claims Nos. 1-18 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

See PCT Rule 67.1(iv).: Methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods.

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form
- ☐ has not been furnished
- ☐ does not comply with the standard

the computer readable form
- ☐ has not been furnished
- ☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in the Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/FI 2004/050034

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	19-33	YES
	Claims		NO
Inventive step (IS)	Claims	19-33	YES
	Claims		NO
Industrial applicability (IA)	Claims	19-33	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Prior art

Reference is made to the following documents:

D1:US 2001/0025139 A1
D2:US 6516225 B1
D3:DE 19517138 A1

Document D1 discloses a cardiac analysis system and diagnostic testing on the heart to evaluate the health of a patient's heart under examination. The system collects multivariate data from contacts (electrodes) distributed on the body and derives from the multivariate a synthetic or composite signal for specific purposes, for example an ECG-signal. The processing compares multivariate signals to a model and/or training data to identify desired features of the signal, where the training data can be any combination of historic, empiric, model or actual data from others or from the subject to be observed. Desired features may include for example P-wave timing, QRS-form, temporal averages etc. (See for example paragraph [0030], [0034], [0046]-[0054] and claim 10.)

Documents D2 and D3 disclose cardiac analysis systems where parameters are calculated from the detected ECG-data.

Statement of reason

The invention according to claims 19-33 discloses a cardiac analysis system and a computer program product where the

.../...

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of: Box V

inventive concept is to acquire an ECG-signal, detect at least one wave from the ECG-signal, namely the P-wave, and calculate parameter values of said wave, said system comprises means for comparing every detected P-wave to a reference P-wave. It is known that the P-wave represents atrial depolarization and that it can show the heart's rate and rhythm. Atrial abnormalities and the P-waves are related to some heart diseases. Prior art systems observe the QRS-complex and the ST-segment ideally, but significant fewer studies have been made concerning the P-wave and its continuous dynamic changes.

The document D1 is regarded as being the closest prior art to the subject-matter of claim 19.

The subject-matter of claim 19 differs from this known cardiac analysis system in that the cardiac analysis system according to claim 19 is adapted to focus to dynamic changes of the configuration of the P-wave and that substantially every detected P-wave is compared to a reference P-wave.

The subject-matter of claim 19 is therefore novel (Article 33(2) PCT).

The problem to be solved by the present invention may be regarded as how to continuously show the in-time coming dynamic changes of the examined P-wave.

The solution to this problem proposed in claim 19 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

Document D1 mentions a possibility to indicate various heart conditions which conditions may include the nature and/or timing of P-waves etc. (See for example claim 10 in D1.) Yet, it is not regarded as obvious to a person skilled in the art that the analysis system in D1 can focus to changes of the configuration of the P-wave on dynamic changes. Also, neither D2 nor D3, independently or in combination with D1, suggest any cardiac analysis system as the one claimed in claim 19.

The above argument is also valid for the invention according to independent claim 32, which therefore is also regarded to be novel and to disclose an inventive step.

.../...

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of: Box V

Claims 20-31 and 33 are dependent on claims 19 and 32 respectively and as such also meet the requirements of the PCT with respect to novelty and inventive step.